



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-4620]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices; Reports of Corrections and Removals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the submission of reports of corrections and removals that are associated with medical and radiation emitting products regulated by FDA's Center for Devices and Radiological Health.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov/>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov/> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov/>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2016-N-4620 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices; Reports of Corrections and Removals.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov/> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov/>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov/> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality,

utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Medical Devices; Reports of Corrections and Removals--21 CFR Part 806

OMB Control Number 0910-0359--Extension

FDA is requesting approval for the collection of information regarding reports of corrections and removals required under part 806 (21 CFR part 806), which implements section 519(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360i(g)), as amended by the Food and Drug Modernization Act of 1997 (FDAMA) (Pub. L. 105-115). A description of the information collection requirements are provided as follows:

Under § 806.10 (21 CFR 806.10), within 10 working days of initiating any action to correct or remove a device to reduce a risk to health posed by the device or to remedy a violation of the FD&C Act caused by the device which may present a risk to health, device manufacturers or importers must submit a written report to FDA of the correction or removal.

Under § 806.20(a), device manufacturers or importers that initiate a correction or removal that is not required to be reported to FDA must keep a record of the correction or removal.

The information collected in the reports of corrections and removals will be used by FDA to identify marketed devices that have serious problems and to ensure that defective devices are removed from the market. This will assure that FDA has current and complete information regarding these corrections and removals to determine whether recall action is adequate. Failure to collect this information would prevent FDA from receiving timely information about devices that may have a serious effect on the health of users of the devices.

Reports of corrections and removals may be submitted to FDA via mail or using FDA's Electronic Submission Gateway (ESG). We estimate that approximately 99 percent of submitters will use the ESG. Our estimate of the reporting and recordkeeping burden is based on Agency records and our experience with this program, as well as similar programs that utilize FDA's ESG.

For respondents for who submit corrections and removals using the electronic process, the operating and maintenance costs associated with this information collection are approximately \$30 per year to purchase a digital verification certificate (certificate must be valid for 1 to 3 years). This burden may be minimized if the respondent has already purchased a verification certificate for other electronic submissions to FDA. However, FDA is assuming that all respondents who submit corrections and removals using the electronic process will be establishing a new WebTrader account and purchasing a digital verification certificate. We therefore estimate the total operating and maintenance costs to be \$30,660 annually (1,022 respondents \times \$30).

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

Activity (21 CFR Part)	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours ²	Total Operating and Maintenance Costs
Electronic process setup ³	1,022	1	1,022	3.08	3,148	30,660
Submission of corrections and removals (part 806)	1,033	1	1,033	10	10,330	

¹ There are no capital costs associated with this collection of information.

² Totals may not sum due to rounding.

³ We estimate that approximately 99 percent of respondents will submit corrections and removals using the electronic process. The actual burden hours for setup of the electronic process listed in the reporting burden table are divided by 3 to avoid double counting in the Office of Information and Regulatory Affairs Consolidated Information System. However, the one-time Average Burden per Response is 9.25 hours, resulting in a total one-time burden of 9,454 hours for the setup of the electronic process.

Table 2.--Estimated Annual Recordkeeping Burden¹

Activity (21 CFR Part)	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Records of corrections and removals (part 806)	93	1	93	10	930

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: March 14, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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